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Implementation of Endovenous Laser Ablation for Varicose Veins in a Large Community Hospital: The First 400 Procedures

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Abstract Endovenous laser ablation (ELA) has become a standard treatment of the incompetent great saphenous vein (GSV). Our prospective audit examines the implementation of this new method in a large community hospital with special attention to obstacles, technical results, pain scores, failures and our learning curve.

Methods: Three hundred and twenty-three patients (403 limbs) with incompetence of the GSV underwent ELA. Patients were assessed by clinical examination and venous duplex ultrasound was performed 6 weeks after operation. Visual analog scale (VAS) pain scores of the first postoperative week were recorded. Operative time and success rate were analysed.

Results: After 6 weeks, 301 (74.7%) treated legs were examined by duplex ultrasound imaging. Successful complete occlusion was present in 282 (93.7%) GSVs. Partial occlusion was present in 12 (4.0%) GSVs. In seven (2.3%) limbs the GSV was not occluded. The maximum mean VAS pain score was noted on the 5th postoperative day. From the start of this series, the operation time decreased rapidly for each surgeon, stabilising after 15 limbs.

Conclusion: ELA of the incompetent GSV is effective and safe. ELA is simple to perform, well accepted by patients and relatively atraumatic. In our opinion, ELA can be easily implemented in surgical practice.

In 2004, we decided to provide an endovenous laser ablation (ELA) service for varicose veins based on published clinical data and patients' demand. Varicose veins are common, arising in 20–25% of women and 10–15% of men above the age of 15.[1] Many patients are asymptomatic or

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seek treatment because of the cosmetic appearance, but symptoms include aching, leg heaviness, pruritus and muscle cramps and may extend to oedema, eczema, lipodermatosclerosis and ulceration.[2,3] By far, the vast majority (60–80%) of varicose veins arise from incompetence of the sapheno–femoral junction (SFJ) and great saphenous vein (GSV) reflux.[4,5] Operations on this system account for 80% of treatments, and 20% are for recurrent venous reflux.[6]

In 1907, Babcock recommended a technique of stripping the dilated vein[7] and, currently, SFJ ligation and GSV stripping remain the standard surgical methods. Stripping the GSV has been shown to reduce the rate of re-operation compared to SFJ ligation and phlebectomies only.[8] Recurrence rates following surgery may vary from 20% to 80%, depending on definition and timing.[9–12] Surgery usually requires general anaesthesia and is associated with significant perioperative morbidity, cost of hospitalisation and delayed return to normal activities and work.[3,9,13,14]

Minimally invasive techniques, such as ELA, have been found to be safe and effective.[15,16] Endovenous delivery of laser energy was first reported in 1999 by Boné,[17] and this technique allows percutaneous treatment of large-diameter saphenous veins as an out-patient procedure under local tumescent anaesthesia, with mild postoperative symptoms.[3,18–20]

In our study, the immediate results of ELA for incompetent saphenous veins are reported following the start of a new service.

Patients and Methods

Patients

The Rijnland Hospital is a large, community training hospital, and approximately 23 000 operations in all specialties are performed here annually. The surgical department consists of eight surgeons and 14 surgical trainees. In the study period between December 2004 and August 2007, 634 patients with symptomatic varicose veins presented to our vascular department. Standard history was noted and physical examinations were performed. All patients were screened by duplex ultrasound scanning to document patency of the deep veins and to evaluate the competence of the superficial veins. Pre- and post-treatment ultrasound investigations were performed by one of the two specialist vascular ultrasonographers from our radiology department using a duplex ultrasound system with a 5–10 MHz linear probe. Reflux was assessed with the patient in the erect position, weight bearing on the other leg, after manual calf compression.

Venous reflux was defined as a reverse flow of more than 0.5 s. Patients with varicose veins due to SFJ and GSV reflux were considered suitable for ELA.

Patients with a history of superficial thrombophlebitis, aneurysmal veins larger than 2.0 cm in diameter, impalpable foot pulses, incompetent perforator veins or deep venous thrombosis (DVT) and those who were pregnant, breast-feeding or in poor general condition were not considered suitable for ELA. After initial consultation and evaluation, patients meeting the appropriate criteria were offered ELA as an alternative to surgery. Subsequently, patients were treated according to their preference. Bilateral treatment was permitted.

Because of the exclusion criteria described above, the clinical, aetiological, anatomical and pathophysiological (CEAP) classification of the treated limbs was $C_{2-6}E_PA_SP_R$. Every patient was, at least, a class 2 according to the CEAP classification devised by the Consensus Group of the American Venous Forum.[21]

Laser technique

All patients were treated with ELA under general or spinal anaesthesia. The patient was positioned in the reverse Trendelenburg position and skin preparation was carried out. The GSV was cannulated near the knee under ultrasound guidance (Sonosite, Bothell, USA) using a 19-gauge needle. The length of the GSV treated and the access point were left to the discretion of the three treating surgeons who selected the most appropriate technique. A guide-wire was passed proximally into the femoral vein and a 5F catheter was positioned under ultrasound imaging 2 cm distal to the SFJ.

Peri-venous tumescent anaesthetic solution was infiltrated along the whole length of the GSV to be ablated with the help of ultrasound guidance. A laser fibre connected to a 980-nm diode laser source (Biolitec AG, Jena, Germany) was inserted via the catheter and also positioned 2 cm distal to the SFJ. After double-checking the position with ultrasound and the red aiming beam of light (635 nm, 4 mW), the laser fibre and catheter were then gradually withdrawn so that the laser energy (15 W power, continuous mode) was delivered uniformly. The pullback speed on the fibre was calculated to achieve an energy rate of at least 50 J cm^{-1}. In the light of subsequently published data, we increased the amount of energy delivered by laser, after 1 year, to achieve higher occlusion rates. Varices and saphenous tributaries were treated by hook phlebectomy (Muller's method) with a maximum of three tiny stab incisions.

Following treatment, a graduated compression stocking, 20–30 mmHg, was applied to the limb for 1 week. Patients were observed for a few hours in the clinic before being discharged with a prescription of 50 mg diclofenac sodium tablets (to be taken thrice daily) for 7 days to reduce inflammatory changes in the GSV and 150 mg Ranitidine to protect the stomach. The patients were encouraged to resume their daily activities (including work) as soon as possible.

Postoperative evaluation

Patients returned to the clinic 1 week after treatment and side effects or complications were recorded. We noted the presence of ecchymosis, palpable induration, phlebitic reaction and pain. Finally, patients were asked whether they would undergo laser ablation again and if they would recommend the procedure to a friend.

Duplex ultrasound assessment was repeated 6 weeks after treatment to assess the success of saphenous ablation. If GSV flow was present, venous reflux was assessed using both Doppler waveform analysis and colour-flow

imaging. Veins showing flow and/or reflux in the treated GSV were considered to be treatment failures. The deep veins were examined for evidence of thrombosis. Three groups of patients were identified: those with a full-length occlusion of the treated GSV (group A); those who had a partial occlusion of the axial vein, irrespective of the reflux status of the SFJ (group B), and those who had no occlusion of the axial vein (group C).

Patients with persisting significant reflux at follow-up were offered a choice of either surgery or repeat ELA.

Assessment of pain

Pain was assessed on days 1–6 using a visual analog scale (VAS) rating of 0 cm (no pain) to 10 cm (worst imaginable pain). This was entered in a diary given to patients at the completion of the procedure and reviewed at the 1-week follow-up. The VAS took the form of 10-cm lines along which patients were invited to make a mark corresponding to the level of maximum pain of the affected leg.

On the same form, the patients were asked to record the consumption of analgesics.

Learning curve

From the beginning, all procedures were performed by three different surgeons (one vascular surgeon and two surgical trainees). All surgeons were experienced in treating varicose veins (at least 50 operations) and were familiar with the Seldinger technique.

In preparation for the new technique, all three had an appropriate duplex ultrasound course lasting 2 days and, before starting ELA in the Rijnland Hospital, the procedure was observed 10 times in another hospital to derive experience regarding the technique.

Operative time (OR), success rate, conversion rate and pain scores were analysed.

OR time was obtained from the anaesthetic records and was defined as the time from the application of the antiseptic skin preparation to the application of the compression stocking.

Data collection and analysis

Data were collected prospectively by one surgical trainee (JvdB) and recorded on a database. The length of the vein treated was calculated with reference to a 20-cm sterile ruler. After each treatment, the total amount of delivered laser energy was displayed (in joules) by the laser device. The quotient of total laser energy in joules and the treated vein length in centimetres was then used to calculate the average, linear endovenous energy density (LEED), expressed in $J\,cm^{-1}$.

Student's *t*-test was used to calculate the difference in LEED among the group with complete occlusion (group A) and the group with no occlusion (group C). The test was two-tailed.

The correlation between the LEED and the mean pain score (VAS) was evaluated with Pearson's test. The SPSS® 12.0 software package (SPSS, Chicago, IL, USA) was used for statistical analysis.

All demographic data are presented as mean ± standard deviation and percentages unless indicated otherwise.

Results

Patients

In the study period, 634 patients with symptomatic varicose veins presented to our vascular department. Patients with varicose veins due to SFJ and GSV reflux were considered suitable for ELA (474 patients, 75%).

Of the 474 patients, 140 (29.5%) were not treated by ELA because of our exclusion criteria. Another 11 patients who were offered ELA preferred to undergo stripping of the GSV.

ELA could not be completed in nine (2.7%) patients. In four patients, the introducer sheath could not be passed cranially because of a stenotic segment in the GSV above the knee due to thrombophlebitis. In two patients, the guide-wire would not pass into a very tortuous and enlarged GSV. In the remaining three patients, the GSV was perforated at the access site, resulting in persistent spasm of the vein. These procedures were then converted into high ligation and stripping of the vein.

Of the 323 patients who eventually underwent ELA of the GSV, 80 (24.8%) underwent bilateral treatment. Patient demographic data and CEAP classifications are listed in Table 1, and operative details are listed in Table 2.

Postoperative evaluation

Side effects were frequent, including haematomas and paraesthesiae. No major complication occurred, and there was no DVT or pulmonary embolism nor skin ulceration. All but one patient said that they would undergo laser ablation again and were positive in recommending the procedure to relatives or friends. The 'dissatisfied' patient had a successful ablation of the GSV, but had a severe headache caused due to spinal anaesthetic leakage.

Duplex ultrasound

After 6 weeks, 301 (74.7%) treated legs were investigated by duplex ultrasound imaging. Successful complete occlusion was noted in 282 (93.7%) of GSVs. Partial occlusion was present in 12 (4%), and seven saphenous veins were open (Table 3). The LEED was similar in successfully treated and open saphenous veins.

Table 1 Patient characteristics and CEAP classification of treated leg

Characteristics[a]	ELA
Number of patients (*n*)	323
Mean age (range)	45.1 years (16–74)
Male: female	29 (9%):294 (91%)
Number of treated legs	403
C1, *n* (%)	0 (0)
C2, *n* (%)	327 (81.1)
C3, *n* (%)	56 (13.9)
C4, *n* (%)	14 (3.5)
C5, *n* (%)	4 (1.0)
C6, *n* (%)	2 (0.5)

[a] Categorical data are presented as *n* and *n* (%) and continuous data as means (range)

Table 2 Operative details

Characteristics[a]	ELA
Mean treated vein length, cm (range)	38 ± 7.3 (12–50)
Tumescent, ml	161 ± 51 (60–350)
Total energy, J	2182 ± 607 (612–3837)
LEED, J cm^{-1} (range)	59 ± 12 (39–93)

[a] Continuous data as means (range) and means with standard deviation (range).

Assessment of pain

The diary with maximum pain scores on a VAS was returned by 203 (62.8%) patients. Of these 203 patients, 58 had bilateral treatment. Totally, 261 treated legs were scored. When questioned by using a VAS pain score of 0–10 (0, no effect; 10, worst pain ever), these patients, on average, graded their pain at 1.64 in the first week. The maximum day-score was noted on the 5th postoperative day (2.06). Pain scores per day are outlined in Fig. 1. The mean VAS scores, calculated per range of LEED, are listed in Table 4. Slightly higher pain scores were found in patients treated with the greatest values of LEED.

Learning curve

Of the three surgeons involved, each carried out more than 90 ELAs over the period studied. Learning curves were created for ELA with the use of the OR time. Fig. 2 shows the change in OR time during this series. Every period represents five treated limbs. In the beginning, the OR time decreased rapidly. After 15 treated limbs, the OR time stabilised. The failures were regularly distributed over all treatments. In the first 30 treatments, every surgeon had one failure. The mean VAS scores in the two periods were similar.

Discussion

ELA was introduced to reduce morbidity compared with conventional SFJ ligation and stripping of the GSV. The action mechanism is heating blood to produce steam, leading to endothelial denudation, collagen contraction and vein-wall fibrosis.[22–25] The efficacy of ELA for the treatment of incompetent GSV has been reported extensively to be greater than 95% in obliterating the saphenous trunk.[23,26]

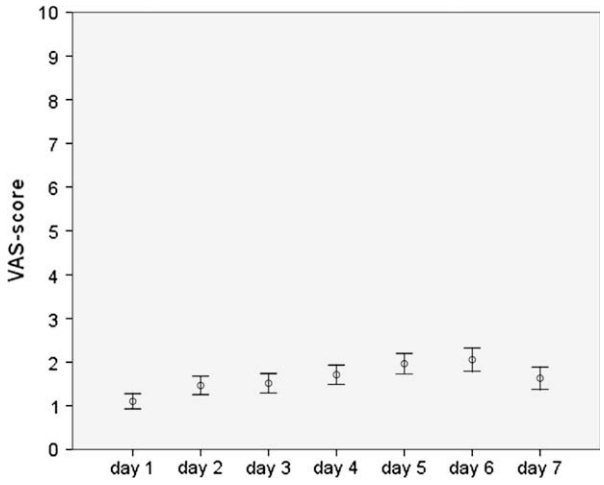

Figure 1 Mean maximum pain scores during the first seven postoperative days. Values are mean maximum scores. The error bars represent the 95% confidence interval.

Our complete occlusion rate is close to this reported result. The failures were uniformly distributed over all treatments. Therefore, we cannot blame the learning curve for not achieving a higher success rate. Despite the lack of an adequate clinical outcome assessment, our study confirms that ELA is technically effective in ablating the great saphenous vein having saphenous reflux.

For the longer term, excellent GSV occlusion rates at 5 years follow-up have been reported, manifested by clinical improvement of symptoms.[27] The frequency of successful ablation seems greater with increasing energy density (ED, J cm^{-1}), and a higher ED does not appear to increase the rate of complications.[28] Treatment failures were observed in patients who received a range of LEED, including those who received doses ≥70 J cm^{-1}.

Previous reports have claimed a good safety record, with minor complications such as transient paraesthesia, skin pigmentation or ecchymosis, induration and self-limiting thrombophlebitis. The over all complication rate is between 0% and 15%.[14,18,29] Serious adverse events, including arterial events, pulmonary embolism, DVT, cutaneous necrosis and ulceration, are rare and none occurred in our series.

Table 3 Success and failures after technically successful endovenous laser treatment of 301 great saphenous veins followed BIJ duplex

	Complete occlusion 282 (93.7%)	Partial occlusion 12 (4.0%)	No occlusion 7 (2.3%)
Length of treated GSV, cm	37 ± 8 (12–50)	39 ± 3 (31–42)	33 ± 8 (20–45)
Energy delivered, J	2125 ± 582 (612–3837)	2346 ± 493 (1426–3038)	1775 ± 461 (1181–2552)
Energy delivered per unit of length, J cm^{-1}	58 ± 9 (39–93)	60 ± 9 (46–72)	54 ± 10 (46–75)

Continuous data presented as mean and standard deviation (range)
A Student's *t*-test was used to calculate the difference in LEED among the group with complete occlusion (group A) and the group with no occlusion (group C). $p = 0.36$. The test was two-tailed.

Table 4 Mean VAS scores calculated per range of LEED in 263 treated legs

Range of LEED, J cm^{-1}	No limbs (%)	Mean pain score VAS
40—49	40	1.54
50—59	128	1.51
60—69	60	1.66
70—79	32	2.14
80—89	3	2.19

The correlation between each individual LEED value and each mean pain score (VAS) was evaluated with Pearson's test ($r = 0.212$).

Few clinical studies on ELA consider post-procedural pain. The difficulty in studying pain is the variation in pain tolerance among patients. Pain is a common occurrence following ELA, and resolves in most patients after a few weeks.[30,31] The pain after ELA does not seem to be correlated to the laser energy deposition.[31] Postoperative pain in the treated leg was found frequently in our series, but the pain scores were low. The pain noted after the procedure was primarily located in the thigh and may have been related to superficial phlebitis, rather than to the ecchymosis. Compared to our previous surgical methods, we did not encounter greater pain scores following the introduction of ELA.

We experienced great patient satisfaction from the beginning. The number of patients with symptomatic varicose veins attending our vascular department increased rapidly after the (locally published) introduction of ELA in our clinic. The numbers increased by 31% and the increase is still in force. All but one responded that they would undergo laser ablation again and were positive in recommending the procedure to relatives or friends. The only patient who was not satisfied had reasons not directly related to the ELA.

The introduction of new techniques has brought interest in the learning curve experienced by surgeons adopting a new method. ELA requires the skill to place the laser fibre at the correct place in the vein but is otherwise technically easy.

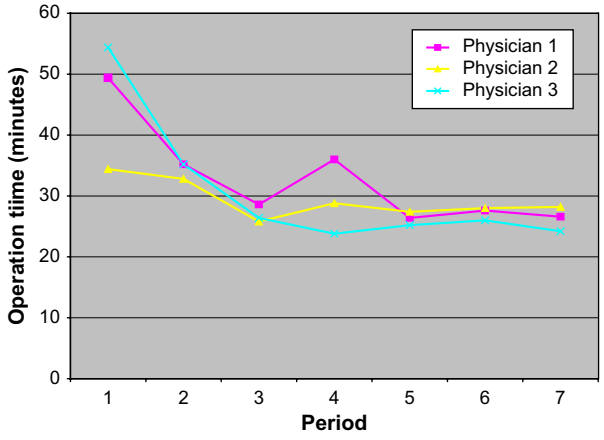

Figure 2 The mean operation time of each individual surgeon expressed for each consecutive period (a period corresponds with five procedures)

The average OR time was 29 min to perform, but at the beginning the OR time was between 50 and 60 min. This decreased rapidly with increasing experience so that, after 15 cases, a level equal to the mean OR time of the last 300 procedures was attained. As a consequence, the introduction of ELA in our hospital had very minimal effects on our OR time schedule.

Conclusion

ELA of the incompetent GSV with a 980-nm diode laser appears to be effective and safe. ELA is simple to perform, well accepted by patients and relatively atraumatic. In our opinion, ELA can be easily implemented in surgical practice as an alternative to the traditional ligation and stripping of the GSV.

Conflicts of Interest

None.

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